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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,268	03/01/2002	Elizabeth Ellen Powell	10338-3 U1 (2508590/vpa/S	3091

570 7590 09/27/2004

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PHILADELPHIA, PA 19103-7013

EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,268	POWELL ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,31,46,55,64 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16,31,46,55,64 and 71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 1-16, 31, 46, 55, and 64 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the detection of distinct target molecules, i.e., nucleic acids and proteins. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 31, 46, 55, and 64, drawn to methods for diagnosing the presence of or a predisposition to developing a fibrotic condition by assaying nucleic acids for the presence of a TGF-beta gene allele or an allele of a gene belonging to the same regulatory pathway as a TGF-beta gene, classified in class 435, subclass 6.

II. Claims 1-16, 31, 46, 55, and 64, drawn to methods for diagnosing the presence of or a predisposition to developing a fibrotic condition by assaying proteins for the presence of a TGF-beta gene allele or an allele of a gene belonging to the same regulatory pathway as a TGF-beta gene, classified in class 435, subclass 7.1.

III. Claim 71, drawn to method for treating or preventing a fibrotic condition comprising administering an agent that modulates the level or activity of a TGF-beta gene allele or an allele of a gene belonging to the same regulatory pathway as a TGF-beta gene, classified, for example, in class 514, subclass 44. Note that further classification cannot be determined without additional information regarding the structure of the agent.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to distinct methods which require performing different method steps and involve the use of different reagents. In particular, the methods of invention I require the use of nucleic acid hybridization probes or primers or sequencing reagents and require performing hybridization or amplification or nucleic acid sequencing reactions in order to detect an allele in a nucleic acid as indicative of the occurrence or predisposition to a fibrotic condition. The methods of invention II require the use of proteins and protein binding reagents, such as antibodies or protein sequencing reagents, and require performing ligand binding assays or protein sequencing assays in order to detect an allele in a protein as indicative of the occurrence or predisposition to a fibrotic condition. The methods of invention III require the use of a therapeutic agent and require administering said agent to a patient in order to accomplish the objective of treating a fibrotic condition.

Each of these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, each invention requires a different non-

patent literature search and sequence search that are not co-extensive. For example, a search for methods which detect a polymorphism in a nucleic acid sequence is not co-extensive with a search for methods which detect a polymorphism in a protein sequence. Additionally, each of these searches would not be co-extensive with a search for methods of administering an agent to treat a fibrotic condition. Therefore, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Further, if Applicants elect invention I or II, these inventions are subject to an additional restriction requirement.

(i) Claims 2-5, drawn to methods for diagnosing the presence of or a predisposition to developing a fibrotic condition by assaying for the presence of a TGF-beta gene allele.

(ii) Claims 6-11, drawn to methods for diagnosing the presence of or a predisposition to developing a fibrotic condition by assaying nucleic acids for the presence of an allele of a rennin-angiotensinogen system gene.

Inventions (i) and (ii) are drawn to patentably distinct methods requiring the use of different reagents and targeting distinct biological molecules. The methods of invention (i) require the analysis of a TGF-beta allele, whereas the methods of invention (ii) require the analysis of a RAS gene allele. The TGF-beta gene is structurally and functionally distinct from RAS genes. These genes do not share a common structural feature or a common functional activity. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

Claims 1, 12-15, 16, 31, 45, 55 and 64 link(s) inventions (i) and (ii). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Each of these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, each invention requires a different non-patent literature search and sequence search that are not co-extensive. A search for alleles of the TGF-beta gene and an association of a TGF-beta allele with a fibrotic condition would not yield all references teaching alleles of RAS genes and an

association between RAS gene alleles and fibrotic conditions, and vice versa. A search indicating that invention (i) is novel or unobvious would not extend to a holding showing that invention (ii) is also novel and unobvious. Similarly, a search indicating that invention (i) is obvious would not extend to a holding

Therefore, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Carla Myers
September 21, 2004

CARLA J. MYERS
PRIMARY EXAMINER